

election requirement was withdrawn as the elected species (i.e., SEQ ID NO: 5) was deemed free of the prior art. The Examiner has now issued rejections of claims 1-7 under 35 U.S.C. §112, first paragraph, acknowledging that the genus for the examination was first searched.

Accordingly, the Examiner should not further restrict claims 1-7 according to individual peptides as the requisite search for the entire genus already was performed in conjunction with the rejections set forth in paper no. 13.

Second, the requirement imposed by the Examiner in paper no. 15 restricts within a single claim, thereby forcing the applicants to file sixty-seven (67) patent applications to cover all of the peptide sequences in claim 1. It has long been held that the Office may not impose a restriction requirement within a single claim. See *In re Watkinson*, 14 USPQ.2d 1407 (Fed. Cir. 1990) *citing In re Weber*, 198 USPQ 328, 332 (CCPA 1978) and *In re Haas*, 198 USPQ 334, 336 (CCPA 1978). The courts have definitively ruled that the statute authorizing restriction practice (i.e. 35 U.S.C. § 121), provides no authority to impose a restriction requirement within a single claim, even if the claim presents multiple independently patentable inventions. In these cases, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Office to fashion such a rejection. As noted in *In re Weber*:

The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim, no matter how broad, which means no matter how many independently patentable inventions may fall within it.

*In re Weber* at 334. Furthermore, as indicated above, the genus has already been searched.

Alleging that a particular claim represents multiple “patentably distinct” inventions is a *de facto* rejection of the patentability of the claim because the claim cannot issue as drafted. In this regard the courts have noted:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not effect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim will never be considered on the merits.

The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than the applicant, it is not inconceivable that a number of fragments would not be described in the specification.

*See In re Weber, supra*, emphasis added.

Here, it should be clear that the exorbitant costs of filing 67 patent applications, which would be required by the present restriction requirement, does not strike an appropriate balance between the administrative concerns of the Office and the applicants' statutory rights as inventors, particularly due to the fact that the genus has already been searched. Accordingly, Applicants respectfully request withdrawal of the restriction requirement in paper no. 15.

Should the Examiner not find the traversal persuasive, in order to be fully responsive, Applicants provisionally elect the peptide of SEQ ID No: 5 with traverse.

Rejections under 35 U.S.C. § 112, first paragraph

In paper no. 15, the Examiner has made no indication that the rejections set forth in paper no. 13 for alleged lack of enablement, utility and written description have been withdrawn. Applicants assume that these rejections are therefore not withdrawn. For this reason, Applicants wish to add further supporting arguments in this response in connection with the enablement and written description rejections.

With respect to the enablement rejections in paper no. 13, Applicants wish to point the Examiner's attention to the specification on page 56, lines 6-8, which states that peptides of SEQ. ID NOs: 1-18 and 25-72 were in fact identified by their translocation activity. Example 2 teaches the person of ordinary skill in the art how to select for peptides generated by the phage display system according to cell translocation activity, and the first portion of Example 3 (i.e., page 55, line 9 to page 56, line 8) states that the peptides having sequences of SEQ ID NOs: 1-81 and 25-72 were identified after three rounds of biopanning according to the procedures set forth in Example 2. Such biopanning procedures detect phage translocation into various types of cells mediated by the peptides of the present invention. For example, SEQ ID NOS: 38-53 were identified by screening translocation activity in human primary T cells; peptides of SEQ ID NOs: 54-63 were identified by screening human epithelial cells (Calu 3 cells); and peptides of SEQ ID NOs: 64-72 were identified by screening translocation activity in surgically resected cervical mucosa tissue from human patients. Thus, it was known that the peptides of SEQ ID NOs: 1-18 and 25-72 had translocation activity at the time they were sequenced. Accordingly, the peptides having sequences of SEQ ID NO: 1-18 and 25-72 were selected based upon their utility of translocating phage into cells, and therefore, the specification fully enables methods for making and using these peptides.

The specification also enables methods of making and using the peptides of SEQ ID NOs: 73, 74 and 75 without undue experimentation because it is stated on page 18, line 21 to page 19, line 15 that the translocation activity of these peptides is characterized using the translocation screening methods that identified a significant number of translocating peptides (i.e., SEQ ID NOs: 1-18 and 25-72). This ability to screen in a routine fashion is probative of a finding of no undue experimentation, and is in complete accordance with the holding in *In re*

*Wands*, which was cited by the Examiner in paper no. 13 in support of the enablement rejection.

The Court of Appeals for the Federal Circuit held in *In re Wand* that the person of ordinary skill in the art was ready and willing to screen vast numbers of antibodies using known screening methods to identify the subset of antibodies appropriate for antigen detection assays. Similarly here, the specification provides screening procedures in Example 2 and these screening procedures were used to identify a significant number of translocating peptides (i.e., SEQ ID NOs: 1-18 and 25-72). This disclosure establishes that the person of ordinary skill in the art could routinely determine the translocation activity of peptides having SEQ ID NOs: 73, 74, and 75, and that no undue experimentation is required. Thus, the specification is completely enabling for the peptides of SEQ ID NOs: 73, 74 and 75 in accordance with the holding in *In re Wands*.

With respect to the written description rejection advanced by the Examiner in paper no. 13, Applicants submit the following. In the *University of California v. Eli Lilly and Co.* decision, it was stated that “[t]he specification only taught certain sequences and therefore, the claims had to be limited to only those DNA sequences described in the specification.” There is no possible interpretation that this statement might preclude equivalents of the peptide sequences claimed. In contrast to the present situation, the patentee in *Lilly* narrowed the claims to a particular species because the specification did not provide adequate structure (i.e., sequences) for a representative number of nucleic acids falling within the genus initially claimed. However, the present specification provides structure in the form of a sequence for each and every peptide claimed, and therefore, the specification provides a description for the entire genus of claim 1 in complete accordance with the *Lilly* decision.

Applicants enclose herewith the fee required for a three month extension of time up to and including May 1, 2003. Applicants believe that no additional fees are required in connection with this communication. However, if any additional fee is required in connection with this communication, the Commissioner is hereby authorized to charge such fee pursuant to 37 C.F.R. §1.17(p) to Deposit Account No. 02-4377. Two copies of this Response are enclosed.

If a telephone interview would be of assistance in advancing the prosecution of the subject application, Applicant's undersigned attorneys invite the Examiner to telephone at the number provided below.

Respectfully submitted,

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